The VacScene

Public Health – Seattle & King County **Immunization Newsletter** Volume 13, Number 2 **Spring 2007**

What's Inside?

The VacScene

Public Health - Seattle & King County
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The VacScene is a publication of Public Health – Seattle & King County written for health professionals. Content is consistent with the most current recommendations from the Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP).

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New Vaccine Protects Against Cervical Cancer, Genital Warts

In early June 2006, the FDA licensed the first vaccine to prevent cervical cancer and genital warts in females caused by genital human papillomavirus (HPV) infection. The quadrivalent vaccine, Gardasil®, protects against HPV types 6,11,16 and 18, which together are responsible for 70% of cervical cancers and 90% of genital warts. On June 29, 2006, the ACIP voted to recommend use of this vaccine in females, ages nine to 26 years.

Genital human papillomavirus is spread by skin to skin contact and is the most common sexually transmitted infection (STI) in the United States, with 20 million persons currently infected and 6.2 million new cases each year. Of these, 74% of new cases occurred among those aged 15-24 years. Modeling estimates suggest that >80% of sexually active women will have acquired genital HPV by age 50 years[1], although not all of these infections are associated with cervical cancer.

The majority of HPV infections are asymptomatic and resolve without treatment, but persistent infection with oncogenic or high risk strains like 16 and 18 can lead to cervical cancer. During 2007, an estimated 11,100 new cases will be diagnosed in the US, and approximately 3,700 women will die from cervical cancer[1]. An average of 57 King County women were diagnosed with cervical cancer annually between 1998 and 2002 and an average of 15 King County women died from cervical cancer annually between 1999 and 2003. Cervical cancer disproportionately affects women who: 1) are of lower socioeconomic status; 2) do not have regular access to health care, 3) are uninsured, and 4) are recent immigrants[2]. In King County, Asian and Pacific Islander women and women in poverty had higher death rates and lower PAP test screening rates.

In clinical trials involving 21,000 women, Gardasil was nearly 100% effective in preventing precancerous cervical, vaginal and vulvar lesions and genital warts caused by human papillomavirus types 6, 11, 16 and 18. Providers must remind their patients to continue with regular cervical cancer screening as the vaccine will not provide protection against all types of HPV that cause cervical cancer, nor will it prevent other STI's.

HPV vaccine is recommended by the ACIP for *routine* use in females 11-12 years of age, although it can be given as early as nine years of age. Catch-up vaccination is recommended for females aged 13-26 years who have not yet been vaccinated. Ideally, the vaccine should be administered before onset of sexual activity. However, females who are sexually active also may benefit from vaccination. Females who have not been infected with any vaccine HPV type would receive the full benefit of vaccination. Females who already have been infected with one or more HPV type would still get protection from the vaccine types they have not acquired. The vaccine has not yet been licensed for males.

Gardasil is administered intramuscularly and can be given at the same time as other vaccines (both live and inactivated). It is contraindicated for those with an immediate hypersensitivity to yeast or any other vaccine component.

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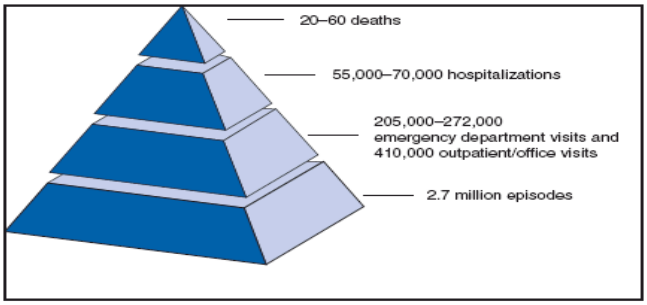
RotaTeq®: Protection Against Rotavirus

Rotavirus infects almost all children by age five and is the most common cause of diarrhea in this age group. Infants between 6 and 24 months are most susceptible. Illness ranges from mild diarrhea to severe watery diarrhea with vomiting, fever and electrolyte imbalance, and rarely results in shock, and death. Transmission is fecal-oral, with symptoms lasting 3-8 days. The cost of emergency room and other physician visits and other direct and indirect costs total nearly one billion dollars annually. (Figure 1).

FIGURE 1. Estimated number of annual deaths, hospitalizations, emergency department visits, and episodes of rotavirus gastroenteritis among children aged <5 years — United States



In February 2006, RotaTeq®, a live oral, human- bovine reassortant rotavirus vaccine, was licensed for use in US infants. In clinical trials, after 3 doses the vaccine was 74% efficacious for rotavirus gastroenteritis of any severity and 98% efficacious against severe rotavirus gastroenteritis. The following are ACIP recommendations for use of this vaccine:

- Infants should be routinely immunized with 3 doses of rotavirus vaccine administered orally at 2, 4, and 6 months.
- IMPORTANT: The first dose should be administered between 6 and ≤12 weeks. **Vaccination should not be initiated for infants >12 weeks.** Subsequent doses should be administered at 4- to 10-week intervals, and **all 3 doses of vaccine should be administered by 32 weeks**.
- Infants with transient, mild illness with or without low-grade fever and infants who are breastfeeding can receive RotaTeq®.
- Infants who have severe hypersensitivity to any component of the vaccine or who have experienced a serious allergic reaction to a previous dose of RotaTeq® should not receive it.

Infants who have had suspected or confirmed rotavirus gastroenteritis before receiving the full course of rotavirus vaccinations should still be immunized because initial rotavirus infections frequently provide only partial immunity. (*Administration tip*: Give Rotateq® prior to injectable vaccines; it's challenging to give an oral vaccine to a crying infant!)

Some children may have mild diarrhea/vomiting within 7 days of receiving the vaccine; moderate or severe reactions have not been associated with RotaTeq®. It is NOT recommended to readminister a dose of rotavirus vaccine to an infant who regurgitates, spits out, or vomits during or after administration of vaccine. The infant can receive the remaining recommended doses of rotavirus vaccine at appropriate intervals.

RotaTeq® was tested in clinical trials with over 71,725 persons specifically to evaluate the risk of intussusception. Thirteen cases of intussusception were observed in the RotaTeq group and 15 cases of intussusception were observed in the placebo group in the one year period following the administration of first dose. As of February 15, 2007, postmarketing surveillance did not suggest association of RotaTeq® vaccination with intussusception. Health care providers and consumers are encouraged to report cases of intussusception to VAERS. For more information on rotavirus and intussusception, please see:
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5610a3.htm?s_cid=mm5610a3_e

Rotavirus vaccine will be available through Washington State's VFC program beginning in May 2007.

MMWR August 11, 2006 / 55(RR12); 1-13 Prevention of Rotavirus Gastroenteritis Among Infants and Children. Recommendations of the Advisory Committee on Immunization Practices (ACIP) at:
http://www.cdc.gov/mmwr/PDF/rr/rr5512.pdf

Pediarix™ and the Interchangeability of DTaP Vaccine Formulations

The recent introduction of combination vaccines raises new issues and challenges regarding how best to use available supplies of these new formulations. Current and future combination vaccines will have unique considerations related to their "fit" into the immunization schedule. In response to questions from clinicians, Public Health is providing additional information and clarification about our current recommendations for use of Pediarix™ **DTaP, IPV, Hepatitis B combination vaccine** and interchangeability of DTaP vaccine formulations.

Availability of Pediarix™ may be limited due to funding constraints. For example, the currently allocated Washington State supply of Pediarix™ is not sufficient to provide a 3-dose series of Pediarix™ for all children eligible for the vaccine. **In order to maximize the number of children who may benefit from this combination vaccine, Public Health recommends administering Pediarix™ at visits when DTaP, IPV *and* Hepatitis B vaccination is indicated.** For example:

- **For children who received the birth dose of hepatitis B vaccine**, Pediarix™ could be administered at 2 and 6 months, and available DTaP vaccine would be used at 4 months*.
- **Availability of Pediarix™ does not change the indication for the birth dose of hepatitis B vaccine, which should be administered.** However, for children who have not received the birth dose of hepatitis B vaccine**,** Pediarix™ could be administered at 2, 4 and 6 months.
  Note: Clinicians are not prohibited from using Pediarix™ at the 4 month visit.

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(Pediarix, continued from p. 2)

What about using different formulations of DTaP-containing vaccine?
The CDC's *Advisory Committee on Immunization Practices (ACIP) General Recommendations on Immunization* (MMWR December 1, 2006 / 55(RR15);1-48, available at: http://www.cdc.gov/nip/publications/acip-list.htm#genrecs), states that although using the same brand of DTaP is desirable whenever feasible, it is permissible to use any DTaP vaccine for the vaccination series. **In fact, since 1999, Washington State's available DTaP formulation has changed 5 times as the contract for state-supplied vaccine has changed.** Inevitably, children who began the series with one product received subsequent doses with another, and this is considered acceptable. CDC experts also advise that it is probably a minority of children who receive a complete series with the same formulation of DTaP.

In this context, health care providers should be aware that new formulations of combination vaccines on the horizon in the US will provide additional options with respect to "fit" into the child immunization schedule. For example, Sanofi Pasteur's DTaP-IPV-Hib combination vaccine, Pentacel™, expected to be licensed for use in the US by the Food and Drug Administration (FDA) in the near future (already licensed in other countries), is designed to be used in a 4-dose primary series at 2, 4, 6, and 15-18 months (independent of considerations related to the hepatitis B vaccination schedule).

- For more information on, Pediarix™, see the January Issue of the *VacScene* newsletter: http://www.metrokc.gov/health/vacscene/vol13-1.htm and WA Department of Health Immunization Program: http://www.doh.wa.gov/cfh/Immunize/documents/vacusage.pdf

For information on Pentacel™ (DTaP-IPV-Hib combination, not yet licensed) presented at the FEB 2007 ACIP meeting, see: http://www.cdc.gov/nip/ACIP/slides/feb07/06-combo-1-joyce.pdf

Vaccines For Children (VFC) Program News

Vaccine Shipment Requirements
As you probably know by now, King County's VFC Program has changed vaccine distributors from GIV to McKesson (along with all of Washington State). So far, there are three important changes resulting from our partnership with McKesson:

1. **Recycle packaging**: Each shipment from McKesson comes to you packaged in a Styrofoam cooler inside a cardboard box. The box protects the cooler so that it can be reused; health care providers are asked to return the cooler in the cardboard box to McKesson. Keep enough packing to meet your needs for (1) vaccine returns, (2) vaccine transport during power outages, and/or (3) transport to offsite clinics. The cost of packaging return will be paid by McKesson.
2. **Shipment frequency**: Health care providers are asked to order all vaccines at one time, including frozen vaccines; when possible, request 110 total doses or more to maximize shipping efficiency. Smaller clinics/practices will find this difficult, and we want to avoid excess doses reaching their expiration date. For those smaller providers, please try to order 60 total doses at a minimum (e.g., six vaccines, 10 doses each), when practical. At the very least, request all vaccines at the same time. Smaller offices such as solo practitioners, teen clinics, or naturopaths using only selected vaccines, are advised to think in terms of quarterly vaccine usage, rather than monthly.
3. **Vaccine returns**: Previously, spoiled and expired vaccine was returned to Public Health. This will now be handled directly by the distributor, McKesson. To return any vaccine whether spoiled, expired or viable:
   - Notify Public Health at (206)296-4774 when you have vaccine to return and a new vaccine return form will be sent to you; the form is also available at http://www.doh.wa.gov/cfh/immunize/documents/vaccinereturnsprovider.xls;
   - Public Health will notify McKesson (they will not accept returns without this notification);
   - Public Health will notify you when you may send the vaccine back to McKesson (in most cases, this will be in the second half of each month);
   - Use McKesson packaging to return vaccine and McKesson will pay shipping costs;
   - Please note that influenza vaccine will not be accepted until after the June 30th expiration date.

Important Vaccine Storage Tip!
Refrigerated vaccines should never be frozen, never exposed to freezing temperatures, and never allowed to come into contact with ice packs or—especially—dry ice**.** When you have to choose between leaving refrigerated vaccines at above-range temperatures or below-range, always choose above-range. The potency of refrigerated vaccines diminishes rapidly at below-freezing temperatures and the vaccine cannot be used. At warmer temperatures, we have more room for error, although leaving it on a countertop is still not a good idea!

The opposite, of course, is true for frozen vaccines (Varicella, MMR, ProQuad [MMR-V]). Do not allow them to thaw; ideally, store them at zero Fahrenheit (0F) or colder. This is especially important for ProQuad because Merck has not yet done out-of-range temperature studies and its stability at temperatures above +5F is unknown. ProQuad, at $75 per dose, is one of the most expensive vaccines offered through Washington State's VFC Programs—use the utmost care storing and handling this (and other!) vaccines.

If you have questions about vaccine storage or need consultation about a potential storage problem, call Public Health at 206-296-4774, 24/7.

Vaccination Resources Mailed to VFC Providers
Each King County VFC provider should have received a large poster mailing box containing a new digital thermometer, a poster of anatomical vaccination sites, and updated order forms.

The new digital thermometers were purchased with Federal immunization program funds provided to Public Health—

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The VacScene Immunization Newsletter

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IMMUNIZATION PROGRAM
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Return Services Requested

PRSTRT STD
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Seattle, WA
Permit No. 1775

Highlights

(New Vaccine Protects…, continued from p. 1)

The three dose series is given as follows: **Dose 1:** Now **Dose 2**: 2 months after Dose 1. **Dose 3**: 6 months after Dose 1.

Side effects include mild or moderate local reactions, such as pain and tenderness at the injection site.

Gardasil will be available through Washington State's VFC program beginning in May 2007.

Merck has included Gardasil among the vaccines available to income-eligible clients through its Patient Assistance Program. Patients 19 years of age and older who lack insurance coverage and meet specific income criteria are eligible to receive Gardasil at no cost from a licensed prescriber (physician, nurse practitioner or physician assistant). The health care provider must work in a private practice or a clinic that is not wholly owned and operated by the government. For more information, call 800-293-3881 Monday-Friday, or visit: http://www.merck.com/merckhelps/vaccines/home.html

The CDC recently updated HPV materials for health care professionals. These materials are available online at: www.cdc.gov/std/hpv/hpv-clinicians-brochure.htm. Additional materials will be sent to VFC providers when the vaccine becomes available.

[1] CDC. Quadrivalent Human Papillomavirus Vaccine Recommendations of the ACIP. MMWR 2007 56:1-24. **http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5602a1.htm?s_cid=rr5602a1_e**

[2] **U.S Cancer Statistics Working Group. *United States Cancer Statistics: 1999-2002 Incidence and Mortality Web-based Report.* Atlanta: U.S. Department of Health and Human Services, CDC and National Cancer Institute; 2005.**

(VFC Program News, continued from p. 3)

Seattle & King County through the Washington State Department of Health Immunization Program CHILD Profile, and are the standard type used in vaccine safety trials. They are more accurate because they show liquid temperatures, rather than air temperatures, in the refrigerator or freezer. Contact Public Health (206-296-4774) if you would like information on purchasing more of these thermometers for your clinic/practice. Please email richard.robles@metrokc.gov if you did not receive your mailing.
(Note: Vaccine requests on outdated forms will be returned).

Influenza Vaccine – Clarification

ACIP now recommends that children younger than age nine years receive two doses of flu vaccine in ***either*** the first ***or*** second year they receive vaccine (*preferably in the first year*). In the past, if they didn't get two doses in the first year, they only got one dose each year thereafter. This recommendation will begin with the 2007-2008 flu season.